

**K082716 A-DEC/W&H ALEGRA AIR-DRIVEN HIGH SPEED HANDPIECE, MODEL TE-97, TE-98, A-DEC/W&H ALEGRA HANDPIECE ATTACHMENT, MODEL HE-43**Jan 15, 2009  
120 days to decisionK082716 · Product code: EFB · Dental  
Source: <https://www.510kdatabase.net/k082716/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Sep 17, 2008
Decision date	Jan 15, 2009
Days to decision	120 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>A-Dec, Inc.</b>
Location	Newberg, OR, US
Contact	THOMAS H LOUISELL
Website	<a href="http://www.a-dec.com/">http://www.a-dec.com/</a>
510(k) history	69 submissions · 69 cleared · 1989-2022

A-Dec, Inc. is a dental equipment manufacturer based in Newberg, Oregon. The company designs and produces integrated dental operatory systems, delivery equipment, handpieces, and mechanical room solutions for dental practices worldwide. A-Dec has maintained a strong FDA 510(k) regulatory record since 1989. The company has received FDA 510(k) clearances from total submissions, with no denied submissions. All cleared devices fall within the Dental category, reflecting the company's specialization in dental equipment and accessories. The latest clearance on record dates to 2...